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20 **IN THE UNITED STATES DISTRICT COURT**
21 **FOR THE EASTERN DISTRICT OF CALIFORNIA**

22 **ASSOCIATION FOR ACCESSIBLE
23 MEDICINES,**

24 Plaintiff,

25 v.

26 **ROB BONTA, IN HIS OFFICIAL
27 CAPACITY AS ATTORNEY GENERAL
28 OF THE STATE OF CALIFORNIA,**

Defendant.

Civil Action No.: 2:20-cv-01708-TLN-DB

**PLAINTIFF'S OPPOSITION TO
DEFENDANT'S MOTION FOR
SUMMARY JUDGMENT**

Date: February 8, 2024
Time: 2 p.m.
Courtroom: 2
Judge: The Honorable Troy L. Nunley
Action Filed: August 25, 2020

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INTRODUCTION

The State’s motion for summary judgment rests on arguments that have been waived, were previously rejected, or are otherwise foreclosed by binding precedent. The Court should deny it.

First, the State has waived any argument that AAM lacks associational standing under the prudential prong of *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333 (1977). It is black-letter law that a challenge to prudential standing may be waived if not timely asserted. The evidence offered in support of the State’s prudential-standing challenge was available when the State opposed AAM’s preliminary injunction motion three years ago on a different standing theory (Article III). Yet the State chose not to raise its prudential-standing argument then, instead waiting until after discovery confirmed that AAM has Article III standing. The State’s failure to raise its prudential-standing defense until after its Article III standing argument was rejected is fatal.

Even if not waived, the State’s argument fails. The State’s assertion that this Court cannot award the relief AAM seeks without the individual participation of AAM members is wrong. This Court did not need individualized proof to decide at the preliminary injunction stage that AB 824 was likely an unconstitutional violation of the Commerce Clause. Nothing about AAM’s claim or the relief it seeks has changed since then. The State’s theory also runs headlong into a wall of precedent. “[C]ourts consistently uphold associational standing in declaratory and injunctive relief cases[,] . . . even where some individual participation is necessary” (e.g., to establish Article III standing). *City of S. Lake Tahoe Retirees Ass’n v. City of S. Lake Tahoe*, 2017 WL 2779013, at *3 (E.D. Cal. June 27, 2017). This case is no different.

The State’s challenges to the merits of AAM’s Commerce Clause claim fare no better. In granting AAM’s motion for preliminary injunction, this Court (correctly) concluded that AB 824 directly regulates patent settlement agreements “in which none of the parties, the agreement, or the pharmaceutical sales have any connection with California.” Dkt. 42 at 15; *see also* Dkt. 47. The Supreme Court recently confirmed in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), that state “law[s] that directly regulate[] out-of-state transactions by those with no connection to the State” exceed “the territorial limits of state authority under the Constitution[.]”

Id. at 376 n.1 (emphases omitted). Far from undermining AAM's claim, Ross confirms that this Court's conclusion at the preliminary injunction stage was correct.

AB 824 is no less unconstitutional today than it was last year. The Court should deny the State's motion for summary judgment and enter a permanent injunction in AAM's favor.¹

BACKGROUND

This Court is no stranger to this case, so AAM only briefly summarizes the lay of the land. AAM filed this lawsuit in August 2020, Dkt. 1, and moved for a preliminary injunction in September 2020, Dkt. 15, challenging California Assembly Bill 824 (2020) on multiple grounds.

AB 824 “creates a presumption that ‘reverse payment’ settlement agreements regarding patent infringement claims between brand-name and generic pharmaceutical companies are anti-competitive and unlawful.” Dkt. 42 at 2; *see* Cal. Health & Safety Code § 134002(a). “It also levies a civil penalty against any individual who assists in the violation of the section of three times the value received by the individual due to the violation or \$20 million, whichever is greater.” Dkt. 42 at 3; *see* Cal. Health & Safety Code § 134002(e)(1). Put differently, AB 824 imposes a *minimum-\$20-million* penalty on anyone who assists in settling a patent suit on terms AB 824 deems verboten, even if the settlement resolves out-of-state litigation involving out-of-state companies.

In opposing AAM’s preliminary injunction motion, the State argued that AAM had “not met its burden of demonstrating Article III standing,” citing *Hunt v. Washington Apple Advertising Commission*, 432 U.S. 333 (1977). See Dkt. 20 at 4. The State also raised a prudential ripeness argument. See *id.* at 8-9. But it did not raise a prudential-standing challenge at any point.

This Court held that at least one AAM member satisfied Article III standing and that AAM had “sufficiently” proved “the elements of associational standing.” Dkt. 42 at 8. The Court also ruled that AAM’s Commerce Clause claim was ripe, that AAM was likely to succeed on the merits of that claim, and that the remaining preliminary injunction factors favored AAM. *See id.* at 5-18.

After this Court granted the State’s motion to modify the injunction’s scope in part, *see* Dkt. 47, the State sought discovery relating only to standing. Discovery closed on July 14, 2023.

¹ The State argues that summary judgment should be entered in its favor on AAM's other claims. AAM respectfully disagrees with this Court's previous resolution of those claims and, to properly preserve for appeal, advances an abbreviated version of its affirmative arguments below.

1 **LEGAL STANDARD**

2 Summary judgment is appropriate if the movant demonstrates that there is no genuine issue
 3 of material fact and the movant is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*,
 4 477 U.S. 317, 327 (1986). The movant bears the burden of showing that there are no genuine issues
 5 of material fact. *Zoslaw v. MCA Distrib. Corp.*, 693 F.2d 870, 883 (9th Cir. 1982); *see McSherry*
 6 *v. City of Long Beach*, 584 F.3d 1129, 1135 (9th Cir. 2009) (summary judgment courts must view
 7 all facts in the light most favorable to the non-movant and draw all inferences in the non-movant’s
 8 favor). A fact is “material” if it “might affect the outcome of the suit under the governing law,” and
 9 a dispute is “genuine” if “the evidence is such that a reasonable jury could return a verdict for the
 10 nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

11 **ARGUMENT**

12 **I. The State’s Eleventh-Hour Prudential-Standing Challenge Is Waived And Meritless.**

13 The State sought discovery only on its Article III standing challenge. And yet, on summary
 14 judgment, the State does not challenge Article III standing. Instead, the State argues *only* that AAM
 15 fails to satisfy the *prudential* requirement that “neither the claim asserted nor the relief requested
 16 requires the participation of individual members in the lawsuit.” Dkt. 68-1 at 6 (quoting *Hunt*, 432
 17 U.S. at 343). The State’s summary judgment motion, filed nearly three years after AAM filed this
 18 lawsuit, is the first time the State has ever raised a prudential-standing argument.

19 **A. The State’s Prudential-Standing Challenge Is Waived.**

20 The only standing argument the State now makes is that AAM fails the third prong of *Hunt*’s
 21 associational standing test, i.e., that “neither the claim asserted nor the relief requested requires the
 22 participation of individual members.” *See* Dkt. 68-1 at 6 (quoting *Hunt*, 432 U.S. at 343); *see also*
 23 *id.* at 6-7. But “the associational standing test’s third prong is a prudential one.” *United Food &*
Com. Workers Union Loc. 751 v. Brown Grp., Inc., 517 U.S. 544, 555 (1996). Article III standing
 25 is jurisdictional and therefore cannot be waived. Prudential standing is different: “[A] party waives
 26 objections to nonconstitutional standing not properly raised before the district court.” *Pershing*
Park Villas Homeowners Ass’n v. United Pac. Ins. Co., 219 F. 3d 895, 899-900 (9th Cir. 2000).
 27 That rule applies with full force here, as “the Supreme Court ruled in *United Food* that *Hunt*’s third
 28

1 prong is prudential and therefore may be waived.” *Ass’n of Christian Schs. Int’l v. Stearns*, 678 F.
 2 Supp. 2d 980, 984 n.5 (C.D. Cal. 2008), *aff’d*, 362 F. App’x 640 (9th Cir. 2010); *see also Mont.*
 3 *Med. Ass’n v. Knudsen*, 581 F. Supp. 3d 1232, 1238 (D. Mont. 2022) (“The first and second prong
 4 of the associational standing inquiry are constitutional, but the third prong is prudential.”).

5 The State waived its prudential standing argument by not raising it until three years into the
 6 case. At the preliminary-injunction stage, the State’s challenge was related only to Article III
 7 standing: it argued that “AAM ha[d] not met its burden of demonstrating Article III standing,”
 8 specifically because (it said) “AAM fail[ed] to demonstrate injury-in-fact and traceability.” Dkt. 20
 9 at 4; *see id.* at 4-7. The State did not raise an individual-participation argument under *Hunt*’s third
 10 prong. That was a strategic choice. The State was clearly aware of *Hunt*, as it began its standing
 11 argument in its brief opposing AAM’s request for an injunction by citing *Hunt* for the proposition
 12 that “for an association to have standing, the association’s members must have standing in their
 13 own right.” *Id.* at 4 (quoting *Hunt*, 432 U.S. at 343). Yet the State chose to challenge only the *first*
 14 prong of *Hunt*’s associational-standing test—which, unlike the prudential third prong, is “*an Article*
 15 *III necessity* for an association’s representative suit,” *United Food*, 517 U.S. at 555 (emphasis
 16 added).

17 In stark contrast, the State now claims that AAM lacks prudential standing because (it says)
 18 “individualized inquiry” is purportedly required “not only with regard to whether the AAM member
 19 is based in California but also whether its counterparty is based in the state.” Dkt. 68-1 at 6-7. The
 20 State could have raised this argument from the beginning, but it failed to do so. The argument is
 21 therefore waived.

22 To be sure, the Ninth Circuit has held that an affirmative defense generally may be raised
 23 for the first time at summary judgment, absent a showing of prejudice. *See Camarillo v. McCarthy*,
 24 998 F.2d 638, 639 (9th Cir. 1993); *Mir v. Levine*, 745 F. App’x 726, 727 (9th Cir. 2018). But the
 25 Ninth Circuit has also held that prudential standing can be waived where “the time and manner in
 26 which” the issue is first “raised” is “strategic.” *Pershing Park*, 219 F.3d at 900. That is exactly the
 27 situation here: The State pursued discovery from AAM and its members that was limited to issues
 28 related to its original Article III standing argument. Only after that discovery confirmed that this

1 Court correctly rejected the State’s Article III standing objection did the State pivot to its prudential
 2 argument—which it could have raised from the start.

3 The State tries to paper over its failure to timely raise the issue by asserting that discovery
 4 “reveal[ed] that the participation of AAM’s members is necessary to determine entitlement to the
 5 remedy AAM seeks.” Dkt. 68-1 at 1. But the facts that were purportedly revealed to the State during
 6 discovery were known or knowable when AAM filed suit. The State’s theory is that some AAM
 7 members “have their principal places of business in California” and others have litigated patent
 8 cases against California companies, and that the presence of those members defeats AAM’s
 9 entitlement to injunctive relief. *Id.* at 6-7. Even if that argument had merit (it does not, for the
 10 reasons explained below), the State cannot reasonably contend that it did not know those facts when
 11 AAM filed its complaint. AAM’s members’ identities and principal places of business are publicly
 12 available, and the information necessary to determine that some are based in California is obviously
 13 available to the State of California. As for the suits against California-based companies, one of the
 14 declarations that AAM filed in support of its preliminary injunction motion *in 2020* disclosed that
 15 that member was engaged in settlement negotiations with a company *headquartered in California*.
 16 Dkt. 15-3 ¶ 5.²

17 The State could have made the prudential standing argument it now presses three years ago.
 18 Its strategic decision not to raise it then, or at any point since, renders the argument waived.

19 **B. Waiver Aside, the State’s Prudential-Standing Argument Is Meritless.**

20 Even if the State had not waived its prudential-standing argument, the argument is without
 21 merit and should be rejected.

22 The State argues that individual proof is necessary to “determin[e] which members [would]
 23 qualify” for relief if AAM prevails in obtaining an injunction. Dkt. 68-1 at 1-2; *see id.* at 6-7. That
 24 argument is wrong. The Ninth Circuit has long held that “[i]ndividualized proof from the members

25 ² This case is unlike *Association of Christian Schools*. See Dkt. 68-1 at 7 (citing case). The
 26 court there allowed the defendants to raise the third *Hunt* prong for the first time at summary
 27 judgment because it was not until then that the plaintiffs asserted “as-applied challenges,” and
 28 “[w]hether an organization satisfies the third *Hunt* prong depends on the claims it asserts and the
 relief it requests.” *Ass’n of Christian Schs.*, 678 F. Supp. 2d at 984-85. Here, by contrast, AAM’s
 claim has been the same from the beginning, as explained further below. *See infra* pp. 9-11.

1 is not needed where, as here, declaratory and injunctive relief is sought rather than monetary
 2 damages.” *Associated Gen. Contractors of Am. v. Metro. Water Dist. of S. Cal.*, 159 F.3d 1178,
 3 1181 (9th Cir. 1998). AAM seeks only declaratory and injunctive relief. Indeed, it obtained a
 4 preliminary injunction two years ago (without the Court assessing individual proof from AAM’s
 5 members). The Court does not need individual proof to convert the preliminary injunction into a
 6 permanent injunction.

7 The State nonetheless contends that AAM fails *Hunt*’s third prong because individualized
 8 proof may be necessary to determine which of AAM’s members will ultimately be able to enforce
 9 the injunction. That is a non-sequitur. It is always the case that, before an individual member of an
 10 association can enforce an injunction that an association has secured on its members’ behalf, the
 11 member must prove that it is among those members actually injured by the defendant on the claim
 12 asserted. But associational standing is not defeated just because some members of an association
 13 would not have standing on their own; *Hunt*’s test “permits the case to go forward even if not all
 14 members of the association would have standing to sue.” Brandon L. Garrett, *Aggregation and*
 15 *Constitutional Rights*, 88 Notre Dame L. Rev. 593, 637 (2012). The State’s speculation that some
 16 AAM members will be unable to enforce the injunction against the State—whether because they
 17 have not recently settled patent infringement cases, they have only settled cases litigated in
 18 California against California entities, or some other reason—does not change the fact that this Court
 19 can grant (and has already granted) AAM’s requested relief without members’ participation.

20 Things would be different if, say, AAM were seeking damages, the quantum of which
 21 varied from member to member. In that case, the Court could not award any relief without
 22 individual members’ participation. *See United Food*, 517 U.S. at 546-47; *United Union of Roofers,*
 23 *Waterproofers, & Allied Trades No. 40 v. Ins. Corp. of Am.*, 919 F.2d 1398, 1400 (9th Cir. 1990).

24 Things would also be different if AAM were challenging the application of AB 824 to
 25 specific patent settlements (rather than the entire class of settlements completed wholly out of state).
 26 *See Hunt*, 432 U.S. at 343 (looking to both “the relief requested” and “the claim asserted”). In that
 27 case, “whatever injury may have been suffered [would be] peculiar to the individual member
 28 concerned, and both the fact and extent of injury would require individualized proof.” *Warth v.*

1 *Seldin*, 422 U.S. 490, 515-16 (1975). That is what was going on in the cases on which the State
 2 relies. In the State’s cases, individual member participation was required to prove the merits of the
 3 underlying *claims*. *See Kan. Health Care Ass’n, Inc. v. Kan. Dep’t of Soc. & Rehab. Servs.*, 958
 4 F.2d 1018, 1022-23 (10th Cir. 1992) (cited at Dkt. 68-1 at 7) (association challenged whether
 5 particular reimbursements to certain members were “adequate and reasonable”); *Rent Stabilization*
 6 *Ass’n of City of N.Y. v. Dinkins*, 5 F.3d 591, 596-97 (2d Cir. 1993) (cited at Dkt. 68-1 at 7)
 7 (association brought as-applied takings claims, and “whether a taking ha[d] occurred depend[ed]
 8 ... also on a variety of financial and other information unique to each landlord”); *Ass’n of Christian*
 9 *Schools*, 678 F. Supp. 2d at 985 (cited at Dkt. 68-1 at 7) (association challenged decision to deny
 10 credit for 38 courses taught by the association’s member schools; the only way to determine
 11 whether the rejections were valid was to evaluate each course individually).

12 But AAM’s claim is nothing like that. AAM is not challenging the application of AB 824
 13 to specific patent settlements. Indeed, this Court’s preliminary injunction orders make that clear.
 14 The only questions this Court needed to resolve to rule for AAM and enter a preliminary injunction
 15 on its Commerce Clause claim (after confirming that Article III standing was satisfied) were pure
 16 questions of law: (1) Does AB 824 directly regulate settlements completed wholly out of state?
 17 (2) Does the Constitution allow California to do that? *See* Dkt. 42 at 10-15 (answering yes and no,
 18 respectively). It did not require “‘ad hoc factual inquiry’ for each member” when the Court
 19 answered those questions two years ago, and it does not require individual factual inquiry now. *Cf.*
 20 *City of S. Lake Tahoe Retirees Ass’n*, 2017 WL 2779013, at *3.

21 That should be the end of the matter. After all, it is black-letter law that *Hunt*’s third prong
 22 is satisfied when an association’s claim “raises a pure question of law” that can be decided without
 23 reference to any particular facts (after confirming that Article III standing is satisfied) and when
 24 the association seeks uniform injunctive relief. *See UAW v. Brock*, 477 U.S. 274, 287-88 (1986).³

25 ³ This Court has previously characterized AAM’s claim as an as-applied challenge. *See*
 26 Dkt. 47 at 14. To be sure, the claim “does not seek to strike [AB 824] in all its applications, but
 27 only to the extent it’ applies to settlements completed wholly out of state.” Dkt. 26 at 5 (quoting
 28 *Doe v. Reed*, 561 U.S. 186, 194 (2010)). It therefore can be considered “as applied” in one sense.
 “But it also ‘is “facial” in that it is not limited to [a] particular [settlement], but challenges
 application of the law more broadly,’ i.e., to *all* settlements completed wholly out of state.” *Id.* (first

1 *Peruta v. County of San Diego*, 2010 WL 2612942 (S.D. Cal. June 25, 2010), is instructive.
 2 There, the California Rifle and Pistol Association Foundation brought a declaratory judgment
 3 action challenging the County’s “refusal to accept self-defense as sufficient ‘good cause’ for a
 4 [concealed-carry] license.” *Id.* at *2. The County argued that the association could not “satisfy the
 5 third prong of the associational standing test because” (it said) “the relief” the association sought
 6 “require[d] ‘individualized proof’ specific to each permit application.” *Id.* The court disagreed.
 7 Contrary to the County’s characterization, the association did “not seek a determination of whether
 8 any specific permit application was properly granted or denied,” but instead sought only “relief
 9 from [d]efendants’ allegedly unconstitutional policy for the public at large.” *Id.* at *3. This, the
 10 court held, “raise[d] a ‘pure question of law’” that the association could “litigate without the
 11 participation of the individual aggrieved claimants and still ensure that ‘the remedy, if granted, will
 12 in[]ure to the benefit of those members of the association actually injured.’” *Id.* (quoting *Brock*,
 13 477 U.S. at 287-88). For that reason, the association’s challenges “equally” affected “all applicants
 14 and potential applicants, including members of the [association],” so there was a “complete identity
 15 between the interests of the [association] and those of its [members] with respect to the issues raised
 16 in this suit.” *Id.* at *2 (quoting *N.Y. State Club Ass’n, Inc. v. City of N.Y.*, 487 U.S. 1, 10 n.4 (1988)).
 17 That was true, moreover, even though not every member of the association had sought a concealed-
 18 carry license or was planning to seek one in the near future. The fact that individual members would
 19 not be able to enforce any ultimate injunction unless they actually suffered injury-in-fact did not
 20 change the fact that the claim the association pressed and the relief the association sought turned
 21 entirely on a pure question of law and thus did not require the participation of any individual
 22 members.

23 The same is true here. All AAM seeks here is an order holding that the State cannot apply
 24 AB 824 against settlements completed outside of California and an injunction to that effect.
 25

26 alteration in original) (quoting *Reed*, 561 U.S. at 194). “Accordingly, the question is whether AAM
 27 can ‘satisfy [the] standards for a facial challenge to the extent of th[e] reach’ that AAM is seeking
 28 to have the law enjoined, … namely, to settlements completed wholly outside of California.” *Id.*
 (ellipsis added) (quoting *Reed*, 561 U.S. at 194). As this Court concluded, the answer to that
 question is yes.

1 Granting that relief against all out-of-state settlements does not require the review of any specific
 2 settlement agreement—as (again) evidenced by the injunction this Court already entered.

3 In sum, not only “can [AAM] litigate [this case] without the participation of” any members
 4 “and still ensure that ‘the remedy, if granted, will injure to the benefit of those members of the
 5 association actually injured,’” it has already done so. *Id.* at *3 (quoting *Brock*, 477 U.S. at 287-88)).

6 **II. Neither The Law Nor The Facts Related To AAM’s Commerce Clause Claim Have
 7 Changed Since This Court Entered The Preliminary Injunction.**

8 **A. Far From Undermining AAM’s Challenge, *Ross* Confirms that this Court’s
 9 Resolution of AAM’s Commerce Clause Claim Was and Is Correct.**

10 This Court previously concluded that AAM was likely to succeed on the merits of its
 11 Commerce Clause claim. Dkt. 42 at 10-15; Dkt. 47 at 3-8. AAM is no less likely to succeed today.
 12 AB 824 has not changed; it still directly regulates settlement agreements completed wholly out of
 13 state. And contrary to the State’s argument, the relevant constitutional law has not changed either.
 14 On the contrary, *Ross* confirms that this Court’s holding at the preliminary injunction stage was
 15 correct.

16 AAM’s Commerce Clause claim is, and always has been, that California lacks constitutional
 17 authority to enforce AB 824 vis-à-vis patent settlement agreements completed wholly out of state.
 18 See, e.g., Dkt. 26 at 5-8; Dkt. 15-1 at 8-10. In ruling for AAM on this claim, this Court principally
 19 relied on the Ninth Circuit’s en banc decision in *Sam Francis Foundation v. Christies, Inc.*, 784
 20 F.3d 1320 (2015), which held that California’s Resale Royalty Act was “facially violative of the
 21 dormant Commerce Clause” as applied to “sales [completed] outside the state of California,” even
 22 though every sale to which that Act applied necessarily involved California residents. Dkt. 42 at
 23 12; see *Sam Francis*, 784 F.3d at 1322-24. As this Court explained, the constitutional defect in
 24 AB 824 is the same as the constitutional defect the Ninth Circuit identified in the Resale Royalty
 25 Act: Both laws *directly regulate* out-of-state transaction because they allow California to hold
 26 parties liable based on “transactions completed wholly out of state.” Dkt. 42 at 14-15.

27 The State does not mention *Sam Francis* in its brief. Perhaps the State believes that *Ross*
 28 implicitly overruled it. It did not.

Unlike AB 824 and the Resale Royalty Act, the law at issue in *Ross* (Prop 12) does not regulate extraterritorially *at all*. All Prop 12 does is ban “the in-state sale of certain pork products.” 598 U.S. at 363. That point was undisputed. *See* 598 U.S. at 376 n.1 (“Petitioners do not allege” that Prop 12 “directly regulate[s] out-of-state transactions” (emphasis omitted)). Instead, their claim was that the *indirect* out-of-state effects of Prop 12’s *purely in-state ban* were so severe as to trigger a purported “‘almost *per se*’ rule against the enforcement of state laws that have ‘extraterritorial effects.’” *Id.* at 390. The Supreme Court unanimously rejected *that* claim, explaining that nothing in the Constitution forbids states from enforcing laws that regulate only in-state conduct just because they have indirect effects elsewhere; after all, “virtually all state laws create ripple effects beyond their borders.” *Id.*

Critically, however, the Court went out of its way to make clear that state laws that *do* directly regulate out-of-state conduct are fundamentally different. The Court was explicit about this. As the Court explained, the “Illinois securities law” at issue in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), exceeded “the territorial limits of state authority under the Constitution” because—just like AB 824—it “‘*directly* regulate[d] transactions which [took] place … wholly outside the State.’” *Ross*, 598 U.S. at 376 n.1 (as in original) (quoting *Edgar*, 457 U.S. at 641-43 (plurality op.)).

The State does not mention this part of *Ross* in its brief. Nor does the State mention this Court’s previous determinations that, in contrast to Prop 12, AB 824 *does* directly regulate out-of-state conduct. *See* Dkt. 42 at 13-15; Dkt. 47 at 4-7. There is no question that AB 824 directly regulates settlement agreements completed out-of-state arising out of out-of-state litigation (just as this Court correctly concluded at the preliminary injunction stage). *Ross* confirms that extraterritorial regulation is unconstitutional.

Indeed, *Ross* relied on the exact distinction this Court drew in ruling for AAM at the preliminary injunction stage. In granting the injunction, this Court distinguished AB 824 (and the Resale Royalty Act) from California’s Low Carbon Fuel Standard law, which the Ninth Circuit upheld in *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070 (9th Cir. 2013). Unlike AB 824, which regulates settlement agreements completed out of state (and the Resale Royalty Act, which regulated sales completed out of state), the Fuel Standard Law regulated only the use and

1 sale of ethanol *in California*. See Dkt. 42 at 12-15. The Court drew the same distinction when
 2 comparing AB 824 with the Shark Fin Law, which the Ninth Circuit upheld in *Chinatown*
 3 *Neighborhood Association v. Harris*, 794 F.3d 1136 (9th Cir. 2015). Unlike AB 824, “the Shark
 4 Fin Law did ‘not attempt to regulate transactions conducted wholly out of state’”; it simply
 5 prohibited the sale of shark fins *in California*. Dkt. 47 at 5 (quoting *Chinatown*, 794 F.3d at 1146).
 6 There were no “allegations from the plaintiffs that the Shark Fin Law regulated actions taking place
 7 entirely outside of California.” *Id.* Hence, “the Ninth Circuit concluded that ‘[t]he Shark Fin Law
 8 does not … require [other] states to adopt California standards[] or attempt to regulate transactions
 9 conducted wholly out of state.’” *Id.* (quoting *Chinatown*, 794 F.3d at 1146).

10 *Ross* drew the same distinction. The Court observed that, like the Shark Fin Law in
 11 *Chinatown* and the Fuel Standard Law in *Rocky Mountain*, Prop 12 does not directly regulate
 12 transactions in other states. All it does is ban “the in-state sale of certain pork products.” 598 U.S.
 13 at 363; *see also id.* at 365-66. *Ross*’s actual holding thus leaves undisturbed the line of Ninth Circuit
 14 cases on which this Court relied in granting injunctive relief. And while *Ross* uses strong language
 15 to reject the purported indirect-effects rule, AAM has never relied upon that nonexistent rule—
 16 precisely because AB 824, unlike Prop 12, directly regulated transactions completed wholly out of
 17 state.

18 In short, AAM, not the State, is entitled to summary judgment on this claim.

19 **B. The State’s Recycled Narrow-Construction Argument Does Not Help Its
 20 Cause.**

21 The State rehashes its argument that the Court should construe AB 824 to apply only to
 22 agreements “in connection with” the sale of products in California. Dkt. 68-1 at 9-13. That
 23 argument is without merit.

24 First, as the State concedes, Dkt. 68-1 at 9, the Court *already rejected this argument*, *see*
 25 Dkt. 47 at 3-7. Nothing about AB 824 (or “California canons of statutory interpretation,” Dkt. 68-
 26 1 at 9, which the Court “agree[d] … it must apply,” Dkt. 47 at 3 n.1) has changed since the Court
 27 ruled one year ago.

28 Second, the State’s atextual construction would not help its cause even if the Court reversed

1 itself and adopted it now. That is for a simple reason: Even under the atextual construction it once
 2 again asks this Court to adopt, the State *explicitly concedes* that AB 824 would still “extend to
 3 agreements entered into out-of-state to the extent that they cover California-based sales.” Dkt. 68-1
 4 at 12 n.5. That concession dooms the State’s argument. “After all, the very definition of ‘directly
 5 regulat[ing]’ … is ‘impos[ing] civil or criminal penalties on non-compliant transactions completed
 6 wholly out of state.’” Dkt. 26 at 6 (ellipsis added) (quoting *Rocky Mountain*, 730 F.3d at 1101-03).
 7 The State’s concession thus confirms that AB 824 *directly regulates transactions that take place*
 8 *wholly out of state*. State laws that ““directly regulate[] transactions which [take] place … wholly
 9 outside the State” exceed “the territorial limits of state authority under the Constitution.” *Ross*, 598
 10 U.S. at 376 n.1 (emphasis in original) (quoting *Edgar*, 457 U.S. at 641-43 (plurality op.)).

11 The State has no answer for this—so it resorts to prevarication. The State asserts that if AB
 12 824 were construed to apply only to the extent a settlement agreement “cover[s] California-based
 13 sales,” then AB 824 would be “materially indistinguishable from Proposition 12, the law upheld in
 14 *National Pork Producers*.” Dkt. 68-1 at 12 & n.5. Not so. Prop 12 regulates only the sale of pork
 15 *in California*. Non-Californian farmers *cannot be sued under Prop 12* and *are not subject to*
 16 *penalties under California law* no matter how small their pig pens are, because *Prop 12 does not*
 17 *apply beyond California’s borders and does not regulate anything other than the sale of pork in*
 18 *the State*. The opposite is true here. Indeed, as this Court recognized at the preliminary injunction
 19 stage, AB 824 *does not regulate the sale of anything*; it only regulates settlement agreements. The
 20 only thing that can be “a violation of [AB 824]” is “an *agreement* resolving or settling … a patent
 21 infringement claim” that includes verboten terms. Cal. Health & Safety Code § 134002(a)
 22 (emphasis added). AB 824 also imposes substantial penalties on “[e]ach person that violates or
 23 assists in the violation,” with “the violation” (again) being an offending patent settlement
 24 agreement, not any sales. *Id.* § 134002(e)(1). Those settlement agreements can violate the law
 25 regardless of whether they were executed in California, involved California companies, or resolved
 26 California litigation. Nothing in the text of the statute links liability to *the subsequent sale of*
 27 *pharmaceuticals*.

28 That defeats the State’s attempt to link to *Ross*. What actually would be “indistinguishable”

1 from AB 824, Dkt. 68-1 at 12, would be if out-of-state farmers could be held liable (and made to
 2 pay California-law penalties) under Prop 12 based on their out-of-state farming activities. But if
 3 that were the case, then *Ross* would have come out the other way even if California promised not
 4 to enforce that law unless an out-of-state farm's pigs were sold in the state. *See Brown-Forman*
 5 *Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 580 (1986) (that a state law is "triggered
 6 only by [in-state] sales" will "not validate" it if it directly "regulates ... out-of-state transactions").

7 The State's reliance on the presumption against extraterritoriality fails for similar reasons.
 8 The State's own authority makes clear that the presumption must give way where the legislature's
 9 intention that a law be "operative, with respect to occurrences outside the state ... is clearly
 10 expressed or reasonably to be inferred 'from the language of the act or from its purpose, subject
 11 matter or history.'" *Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191, 1207 (2011) (quoting *Diamond*
 12 *Multimedia Sys., Inc. v. Super. Ct.*, 19 Cal. 4th 1036, 1059 (1999)). And it is more than just the
 13 plain language here. AB 824's legislative history states that "this bill would regulate settlement
 14 agreements that may occur in other states and may involve parties located in and operating out of
 15 other states." Dkt. 68-3 at 16 (Ex. A at 12). And the State confirmed at oral argument in the Ninth
 16 Circuit in the initial round of litigation that it intends to enforce AB 824 "with respect to agreements
 17 made outside the borders of California." Dkt. 15-2 at 22:10-23:24. This case is thus far afield from
 18 the presumption cases the State invokes. *See, e.g., Sullivan*, 51 Cal. 4th at 1207 (presumption
 19 unrebutted where "[n]either the language of the UCL nor its legislative history provides any basis
 20 for concluding the Legislature intended the UCL to operate extraterritorially"); *Sarviss v. Gen.*
 21 *Dynamics Info. Tech., Inc.*, 663 F. Supp. 2d 883, 898 (C.D. Cal. 2009) (finding "no 'clear
 22 express[ion]' of extraterritorial application for California wage and hour laws" and accordingly
 23 holding the "presumption against extraterritorial application unrebutted").

24 In all events, even if the presumption against extraterritoriality applied here, all that would
 25 mean is that AB 824 does not reach out-of-state *agreements*—leading to the same result already
 26 reached by this Court: AB 824 can only apply to patent litigation settlement agreements

27
 28

1 “negotiated, completed, or entered into within California’s borders.” Dkt. 47 at 8.⁴

2 **C. The State’s Recycled Antitrust-Specific Argument Does Not Help It Either.**

3 As a last-ditch effort, the State rehashes its argument that AAM’s Commerce Clause claim
 4 (and the injunction that has been in place for 20 months) somehow “runs contrary to the long history
 5 and tradition of states regulating antitrust and unfair competition.” Dkt. 68-1 at 13-14. This recycled
 6 argument, *see* Dkt. 20 at 9-10, fares no better now than it did before, *see* Dkt. 26 at 6-7.

7 To start, state antitrust law is not exempt from the Constitution. No federal appellate court
 8 has *ever* held that a state may use its antitrust law to directly regulate agreements completed wholly
 9 out of state just because they may have downstream, in-state effects. In fact, all courts of appeals
 10 to confront the issue directly—including some the State cites—have reached the opposite
 11 conclusion: While state “antitrust and unfair competition statutes” may constitutionally be applied
 12 to conduct that takes place at least partially in state, *Knevelbaard Dairies v. Kraft Foods, Inc.*, 232
 13 F.3d 979, 993-94 (9th Cir. 2000) (cited at Dkt. 68-1 at 14) (upholding application of California
 14 antitrust law to “conduct” that partially “took place … in California”), state law “cannot regulate
 15 [transactions] that take place wholly outside it,” *In re Brand Name Prescription Drugs Antitrust*
 16 *Litig.*, 123 F.3d 599, 613 (7th Cir. 1997) (cited at Dkt. 68-1 at 14).

17 Furthermore, AB 824 is not the mirror image of state antitrust law. As AAM has explained,
 18 *see* Dkt. 26 at 6-8, AB 824 does not simply alter the presumption and penalties applicable to
 19 conduct that was already illegal under California antitrust law; it creates a new violation of the
 20 Health and Safety Code with a distinct statute of limitations and a distinct set of reporting
 21 requirements. What is more, AB 824 does not even regulate the same thing as the Cartwright Act

22 ⁴ *Russo v. APL Marine Services, Ltd.*, 135 F. Supp. 3d 1089 (C.D. Cal. 2015), *aff’d*, 694 F.
 23 App’x 585 (9th Cir. 2017) (cited at Dkt. 68-1 at 11), confirms the point. The relevant statutes there
 24 did not impose a “residency requirement on either the employer or the person aggrieved” or any
 25 “limitation based on where the conduct occurred.” *Id.* at 1094. So, to determine the “extraterritorial
 26 application” of those laws, the court turned to the regulated conduct—*i.e.*, “the situs of both
 27 employment and the material elements of the cause of action.” *Id.* The presumption thus arose that
 28 those employment laws did “not apply when the tortious conduct and situs of employment are
 outside of California.” *Id.* Here, the conduct AB 824 makes unlawful is a patent settlement
 agreement that contains terms that AB 824 considers improper. Therefore, even if the presumption
 of extraterritoriality was not rebutted, that presumption would apply to the *regulated conduct*,
 thereby limiting AB 824’s reach to offending patent litigation settlement agreements negotiated,
 completed, or entered within California.

(California’s antitrust law). “[T]he ‘transaction or occurrence’ proscribed by the Cartwright Act includes not only the sale of price-fixed goods, but the full extent of incipient conspiratorial conduct described in section 16720 of the Act.” *AT&T Mobility LLC v. AU Optronics Corp.*, 707 F.3d 1106, 1110 (9th Cir. 2013). But that is not true of AB 824; *only* a settlement agreement that contains terms of which AB 824 disapproves, *not subsequent sales of drugs*, can violate AB 824. *See Cal. Health & Safety Code § 134002(a); see also* Dkt. 15-2 at 28:14-20. Accordingly, far from disturbing any settled common law, holding that AB 824 is unconstitutional to the extent it “*directly regulate[s]* transactions which [take] place … wholly outside the State,” will simply enforce “the territorial limits of state authority under the Constitution.” *Ross*, 598 U.S. at 376 n.1.

III. The Merits Of AAM’s Other Claims Are Unchanged, But AAM Continues To Believe That This Court Incorrectly Resolved Them And Should Now Grant AAM Summary Judgment On All Of AAM’s Claims, Not Just Its Commerce Clause Claim.

Although the Court agreed with AAM that AB 824 exceeds the limits of California’s authority by directly regulating out-of-state transactions, it rejected AAM’s claims that AB 824 (1) is preempted; (2) violates the Eighth Amendment Excessive Fines Clause; and (3) violates due process by creating an insurmountable burden-shifting regime. *See* Dkt. 47 at 8-14. AAM respectfully disagrees with the Court’s resolution of those claims. But because the legal merits of those claims do not turn on any disputed facts, and nothing about the law has changed since last February, AAM does not repeat in full arguments this Court has already rejected. Instead, AAM hereby incorporates by reference as if fully set forth herein its arguments set forth in its Memorandum In Support of Motion for Preliminary Injunction and related briefing, *see* Dkt. 15-1 at 10-18; Dkt. 26 at 8-10 and summarizes the arguments below only to ensure preservation.

A. AB 824 Is Preempted.

AB 824 is preempted by: (1) the Patent Act; (2) the Hatch-Waxman Act; (3) the Supreme Court’s careful balancing in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); and (4) the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”). *See* Dkt. 15-1 at 10-15.

The Patent Act. AB 824 conflicts with two key provisions of the Patent Act by (a) taking the exercise of the federally conferred right to grant an exclusive license and making that presumptively unlawful, *compare* Cal. Health & Safety Code § 134002(a)(1)(A), *with* 35 U.S.C.

1 § 261, and (b) removing the ordinary federal presumption of patent validity, *compare* Cal. Health
 2 & Safety Code § 134002(b)(2), *with* 35 U.S.C. § 282(a). *See* Dkt. 15-1 at 10-14.

3 First, it is indisputable that the Patent Act grants patent holders the *right* to grant exclusive
 4 licenses. *See* 35 U.S.C. § 261. Indeed, “[u]nquestionably, the owner of a patent may grant licenses
 5 to manufacture, use, or sell upon conditions not inconsistent with the scope of the monopoly.” *Gen.*
 6 *Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181 (1938). But, under AB 824, a patent
 7 litigation settlement related to a pharmaceutical product that contains an exclusive license—and
 8 nothing else—is presumptively suspect unless it permits the generic manufacturer to bring its
 9 generic drug onto the market immediately. The conflict is clear, especially after the Supreme Court
 10 admonished that patent holders’ exclusive license right should be respected, *see Actavis*, 570 U.S.
 11 at 158. AB 824 takes a right conferred by Congress and makes it presumptively unlawful.

12 Second, whereas the Patent Act requires that “patent[s] shall be presumed valid,” 35 U.S.C.
 13 § 282(a), AB 824 prohibits factfinders from presuming that “any patent is enforceable,” Cal. Health
 14 & Safety Code § 134002(b)(2); *see* Dkt. 15-1 at 11. To be sure, the Patent Act by its terms speaks
 15 only of a presumption of validity, not enforceability. But courts read Section 282(a)’s presumption
 16 that a patent is “valid” to also include enforceability. *See, e.g., Conmed Corp. v. Lexion Med., LLC*,
 17 2019 WL 3891026, at *1 (N.D.N.Y. Aug. 19, 2019) (citing § 282 for proposition that patent “was
 18 presumed valid and enforceable”); *Govino, LLC v. WhitePoles LLC*, 2017 WL 6442187, at *9 (N.D.
 19 Cal. Nov. 3, 2017), *report and recommendation adopted*, 2017 WL 6442188 (N.D. Cal. Dec. 11,
 20 2017) (same); *DealerTrack, Inc. v. Huber*, 2008 WL 11337833, at *1 (C.D. Cal. July 21, 2008) (“A
 21 patent is presumed to be valid and enforceable.”). AB 824 therefore directly diminishes the value
 22 of a federally conferred patent. The fact that AB 824 is not offering “patent-like protection,” Dkt. 47
 23 at 9, does not save it from invalidation under the Supremacy Clause. *See Bonito Boats, Inc. v.*
 24 *Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) (“[S]tate regulation … must yield to the extent
 25 that it clashes with the balance struck by Congress in our patent laws.”); *Morseburg v. Balyon*, 621
 26 F.2d 972, 977 (9th Cir. 1980) (state laws regulating “competition” have long been “held to be
 27 preempted by the federal patent law” when they “upset the federally struck balance”). By removing
 28 the presumption that a patent is valid and enforceable, AB 824 undermines patent protections and

1 skews the delicate balance at the heart of federal patent law. It is preempted. *See Buckman Co. v.*
 2 *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *see also* Dkt. 15-1 at 11.

3 **The Federal Balance Regulating Generic Market Entry.** In addition to conflicting with
 4 Patent Act directly (and thereby diminishing the value of a federally conferred intellectual property
 5 right), AB 824 upsets the federal balance at the heart of the federal laws regulating the market-entry
 6 mechanism for generic pharmaceuticals, and is therefore preempted for all the reasons stated in
 7 AAM's Memorandum in Support of Motion for Preliminary Injunction and related briefing. *See*
 8 Dkt. 15-1 at 12-14; *see also* *Farina v. Nokia Inc.*, 625 F.3d 97, 123 (3d Cir. 2010) ("The Supreme
 9 Court's preemption case law indicates that ... a finding of conflict preemption" is particularly likely
 10 when the regulatory environment demands "a balance between competing statutory objectives.").

11 *Contra* Dkt. 68-1 at 16, there is nothing "speculative" about this challenge. Indeed, the State
 12 itself goes on to concede that "[p]reemption is a pure question of law" that this Court can and should
 13 resolve now. *Id.* at 16 n.7. And courts across the country have recognized that because questions of
 14 preemption are "predominantly legal," they are appropriate for pre-enforcement adjudication. *Pac.*
 15 *Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 201 (1983).
 16 Regardless, the Court need not wait around to see the impact of AB 824—because we have already
 17 seen it. AB 824 has made it costlier, riskier, and more difficult to enter into patent-litigation
 18 settlements that help speed generics onto the market, which inevitably will diminish the incidence
 19 of such transactions and the incidence of generics entering the market prior to patent expiry. *See*
 20 Dkt. 15-1 at 13-14. The declarations submitted make this clear, *see* Dkt. 15-5 (Sealed) ¶¶ 4-5;
 21 Dkt. 15-6 (Sealed) ¶¶ 3-5. AB 824 conflicts with the Hatch-Waxman Act and is preempted.

22 That is not all; AB 824 is also inconsistent with the federal balance struck in the Patent Act
 23 and respected in *Actavis*. The State argues that *Actavis* only "determined ... the level of scrutiny
 24 pay-for-delay agreements should receive under *federal* antitrust law" and therefore "is not binding
 25 on states" and does not "prohibit states from subjecting sales affected by pay-for-delay agreements
 26 to the same or differing levels of scrutiny under state antitrust statutes." Dkt. 68-1 at 16. But *Actavis*
 27 did not turn solely on questions of antitrust law; instead, "patent and antitrust policies [were] both
 28 *relevant*" to whether a pharmaceutical patent settlement could be subjected to antitrust-style

scrutiny. *Actavis*, 570 U.S. at 148 (emphasis added). As federal rights are implicated in cases seeking to hold parties liable for settling patent suits, “courts must ‘balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of [antitrust law] against combinations and attempts to monopolize.’” *Id.* (citation omitted). California simply does not have the authority to strike a new balance between competition law and federal patent law as it relates to patent-litigation settlements. *See Bonito Boats*, 489 U.S. at 152.

BPCIA. AB 824 is also preempted to the extent it purports to apply to patent settlements involving biologics and biosimilars under the BPCIA. The State’s argument to the contrary depends on a simple mischaracterization of the statute. According to the State, the BPCIA does not preempt AB 824 because “BPCIA only preempts state claims related to compliance with the specific BPCIA processes” and (it says) “AB 824 employs “antitrust law to target sales affected by pay-for-delay settlements—not any element of the BPCIA process.” Dkt. 68-1 at 17. But as explained at length above, AB 824 does not use “antitrust law to target *sales*”; all AB 824 actually regulates are patent litigation settlements. *See supra* pp. 11-14. And the Federal Circuit has clearly held that state regulation of “biosimilar patent litigation,” including “the field of patent dispute *resolution* triggered by the filing of a biosimilar application,” is categorically off-limits because “the federal government has fully occupied this field.” *Amgen Inc. v. Sandoz Inc. (Amgen II)*, 877 F.3d 1315, 1327-28 (Fed. Cir. 2017). As a result, California’s attempt to regulate patent litigation settlements related to biosimilar patents is preempted. *See also* Dkt. 15-1 at 14; Dkt. 26 at 9.

B. AB 824 Violates the Prohibition on Excessive Fines.

This Court previously found—and the State continues to argue—that AAM’s “Excessive Fines claim is not ripe for adjudication.” Dkt. 47 at 13; Dkt. 68-1 at 17-18. But, as explained previously, AAM’s facial challenge is that there are *no set of circumstances* under which the *minimum* \$20-million penalty AB 824 imposes could be constitutionally applied to a person who has not received anything of value as a result of his or her assistance. *See, e.g.*, Dkt. 15-1 at 16 (citing *Reed*, 561 U.S. at 194). No additional facts are required to answer that question—and there is no prudential reason to postpone adjudication. Just the opposite. If this issue is not resolved now, before a state-enforcement action is initiated, then aggrieved individuals will have no avenue to get

1 into federal court to challenge the constitutionality of AB 824's penalties. *See id.* at 12 (citing
 2 *Younger v. Harris*, 401 U.S. 37, 41 (1971); *Middlesex Cnty. Ethics Comm. v. Garden State Bar*
 3 *Ass'n*, 457 U.S. 423, 439 (1982); *Steffel v. Thompson*, 415 U.S. 452, 475 (1974)).

4 The State's argument that "AAM's Excessive Fines challenge fails on the merits" because
 5 (it says) AB 824 penalizes only a "party to an agreement, ... not natural persons," Dkt. 68-1 at 18,
 6 is belied by the statute's plain text. AB 824 provides that "[e]ach *person* that violates or *assists* in
 7 the violation of this section"—even when that person "has not received anything of value"—is
 8 subject to a minimum-\$20-million penalty. Cal. Health & Safety Code § 134002(e)(1)(A). The
 9 statute means what it says. And there can simply be no argument that such a penalty could ever be
 10 constitutional with respect to an individual "person" that merely "assists" with a settlement effort
 11 and receives nothing of value therefrom. *See id.* Thus, although the State tries to limit AB 824's
 12 penalty provisions' reach to the "party to an agreement," Dkt. 68-1 at 18, the fact that the State does
 13 not disclaim its unconstitutional statutory authority to impose its \$20-million penalty on individuals
 14 is illuminating and focuses the immediacy of this dispute, *see* Dkt. 26 at 9.

15 **C. AB 824's Burden-Shifting Regime Violates Due Process.**

16 For all the reasons previously stated, *see* Dkt. 15-1 at 17-18; Dkt. 26 at 10, AB 824 violates
 17 due process by erecting what amounts to an irrebuttable presumption of liability and by removing
 18 the most basic antitrust defense (i.e., the procompetitive effects of the conduct will outweigh any
 19 short-term barriers to competition). *See Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007).

20 **CONCLUSION**

21 For the foregoing reasons, the Court should deny the State's motion for summary judgment.

22

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1 Dated: November 6, 2023

Respectfully submitted,

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1 **CERTIFICATE OF SERVICE**

2 I hereby certify that on this 6th day of November, 2023, I electronically filed the foregoing
3 Plaintiff's Opposition to Defendant's Motion for Summary Judgment with the Clerk of the Court
4 for the United States District Court for the Eastern District of California using the CM/ECF system.
5 I certify that all participants in this case are registered CM/ECF users and that service will be
6 accomplished by the CM/ECF system.

7
8 /s/ Michael Shipley

9 Michael Shipley

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